

RESULTS OF INVESTIGATION: Analysis showed that the article contained no N-(caprylaminoformylmethyl)-Pyridinium Chloride.

LBELED: 11-17-55, N. Dist. Ill.

CHARGE: 502 (a)—the label statement "Active Ingredients \* \* \* N-(caprylaminoformylmethyl)-Pyridinium Chloride\* 1:2000" was false and misleading; and 505 (a)—the article, when shipped, was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 2-8-56. Default—destruction.

4985. B & H inhalant powder. (F. D. C. No. 38747. S. No. 25-796 M.)

QUANTITY: 8 display placards, 21 vials each, and 2 cartons, 3 vials each, at Minneapolis, Minn.

SHIPPED: 5-23-55, from Billings, Mont., by B & H Laboratories.

LABEL IN PART: (Vial) "B & H Inhalant Powder Contains borate soda, silver nitrate, menthol."

ACCOMPANYING LABELING: Cards designated "Colds Asthma Hay Fever Headaches Sinus B & H Inhalant Powder 'Amazing Discovery'" and leaflets entitled "Sinus And Hay Fever Sufferers B & H Inhalant Powder."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 98.1 percent borax, 1.86 percent silver nitrate, and a small amount of menthol.

LBELED: 12-16-55, Dist. Minn

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for colds, asthma, hay fever, and all kinds of headaches and sinus trouble; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 2-3-56. Default—destruction.

## DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

### DRUGS FOR HUMAN USE

4986. Various drugs. (F. D. C. No. 38907. S. Nos. 37-041/2 M, 37-045 M 37-048 M, 37-056/9 M, 37-061 M, 37-063 M, 37-067/9 M, 37-073/83 M 37-085 M, 37-087/8 M.)

QUANTITY: 2 btls. containing a total of 1,650 *Roncovite tablets*; 4 btls. containing a total of 5,000 *Zilatone tablets*; 3 btls. and 1 drum containing a total of 28,000 *Creamalin tablets*; 1 btl. containing 800 *Pheno-Bepadol tablets*; 9 100-capsule btls. of *Fer-Dona capsules*; 2 btls. containing a total of 1,000 *Kiophyllin tablets*; 2 btls. containing a total of 650 *Pavatrine tablets*; 2 btls. containing a total of 4,000 *Amodrine tablets*; 1 1,100-capsule btl. of *Sulphocol capsules*; 6 btls. of *Hemosule capsules*; 2 btls. containing a total of 1,360 *Butisol Sodium capsules (Mol-Iron tablets)*; 1 1,100-capsule btl. of *Propadrine capsules*, 92 vials of *Dibenzylethylenediamine dipenicillin G oral suspension*; 2 btls. containing a total of 200 *Bicillin-Sulfas tablets*; 1 btl. containing 109 *Sulfabiotic tablets*; 1 btl. of *Pansulfa with penicillin tablets*; 1 btl. of *Aureomycin Spersoids*; 8 envelopes containing a total of 700 *Diamox tablets*; 2 btls. of *Erythrocin*; 3 btls. of *Thorazine*; 3 boxes of *Aureomycin capsules*; 2 btls.

containing a total of 530 *Cortril tablets*; 5 60-cc. btl. of *pediatric Chloromycetin Palmitate*; 9 btl. of *penicillin Solvets*; 34 1-oz. btl. of *Paredrine-Sulfathiazole Suspension*; 2 btl. containing a total of 1,800 *Ventrex Kapseals*; and 4,200 *AM Plus capsules* in btl. and cartons, at Newark, N. J.

SHIPPED: On unknown dates, from Chicago, Ill., Indianapolis, Ind., Detroit, Mich., Cincinnati, Ohio, Philadelphia, Pa., and Brooklyn, Buffalo, and New York, N. Y.

LIBELED: 1-13-56, Dist. N. J.

CHARGE: 501 (c)—(*Pheno-Bepadol tablets*) the strength of the article differed from that which it purported and was represented to possess, namely, vitamin B<sub>1</sub> (thiamine) 3 milligrams; (*Fer-Dona capsules*) the vitamin B<sub>1</sub> content of the article fell below the labeled potency in vitamin B<sub>1</sub>; (*Hemosule capsules*) the vitamin B<sub>1</sub> and C content of the article fell below the professed potency in vitamin B<sub>1</sub> and C; (*Ventrex Kapseals*) the vitamin B<sub>1</sub> content of the article fell below the professed potency in vitamin B<sub>1</sub>; and (*AM Plus capsules*) the dextro-amphetamine sulfate, thiamine hydrochloride, and ascorbic acid content of the article fell below the professed potency in these substances.

502 (a)—(*Pheno-Bepadol tablets*) the label statement "Each Tablet contains: \* \* \* vitamin B-1 (Thiamine) 3 milligrams" was false and misleading as applied to a product containing less than the declared amount of vitamin B<sub>1</sub> per tablet; (*Fer-Dona capsules*) the label statement "Six Capsules \* \* \* Contains: \* \* \* Vitamin B-1 2 mg." was false and misleading as applied to a product which contained not more than 1.5 milligrams of vitamin B<sub>1</sub> per 6 capsules; (*Hemosule capsules*) the label statement "Each Capsule Contains: \* \* \* Thiamine HCl (Vitamin B<sub>1</sub>) 1.0 mg. \* \* \* Ascorbic Acid (Vitamin C) 15.0 mg." was false and misleading as applied to a product which contained 0.74 milligram of vitamin B<sub>1</sub> and 10 milligrams of vitamin C per capsule; (*Mol-Iron tablets*) the label statement "Each Tablet Contains: Ferrous Sulfate (3 gr.) 195 mg. Molybdenum Oxide (1/20 gr.) 3 mg." was false and misleading as applied to a product which contained no ferrous sulfate or molybdenum oxide; (*Ventrex Kapseals*) the label statement "Each Kapseal Represents: \* \* \* Vitamin B<sub>1</sub> (Thiamine HCl) 0.5 mg." was false and misleading as applied to a product which contained 0.22 milligram of vitamin B<sub>1</sub> per Kapseal; and (*AM Plus capsules*) the label statement "Each Capsule Contains Dextro-Amphetamine Sulfate 5 mg. \* \* \* Thiamine Hydrochloride 2 mg. \* \* \* Ascorbic Acid 37.5 mg." was false and misleading as applied to a product which contained no dextro-amphetamine sulfate, 1.3 milligrams of thiamine hydrochloride, and not more than 30 milligrams of ascorbic acid per capsule.

502 (b) (1)—(*Roncovite tablets*, *Creamalin tablets*, *Kiophyllin tablets*, *Pavatriline tablets*, *Amodrine tablets*, *Propadrine capsules*, *Bicillin-Sulfas tablets*, *Diamox tablets*, *Erythrocin*, *Thorazine*, and *Cortril tablets*) the labels failed to bear the names and places of business of the manufacturers, packers, or distributors.

502 (d)—(*Pavatriline tablets*, *Amodrine tablets*, and *Butisol Sodium capsules* [*Mol-Iron tablets*]) the articles contained a derivative of barbituric acid, and their labels failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

502 (e) (2)—(*Roncovite tablets*, *Zilatone tablets*, *Creamalin tablets*, *Kiophyllin tablets*, *Pavatriline tablets*, *Amodrine tablets*, and *Diamox tablets*) the labels failed to bear the common or usual name of each active ingredient.

502 (f) (1)—(*Roncovite tablets, Zilatone tablets, Creamalin tablets, Kiophyllin tablets, Pavatrine tablets, Sulphocol capsules, Mol-Iron tablets, Propadrine capsules, Diamox tablets, and Paredrine-Sulfathiazole Suspension*) the labeling failed to bear adequate directions for use.

502 (f) (2)—(*Propadrine capsules*) the labeling failed to bear adequate warnings to prevent misuse.

502 (1)—(*dibenzylethylenediamine dipenicillin G oral suspension, penicillin Solvets, Bicillin-Sulfas tablets, Sulfabiotic tablets, and Pansulfa with penicillin tablets*) the articles were represented as drugs composed in part of penicillin, and they were not from batches with respect to which certificates issued pursuant to law were effective; (*Aureomycin Spersoids and Aureomycin capsules*) the articles were represented as drugs composed in part of chlortetracycline, and they were not from batches with respect to which certificates issued pursuant to law were effective; and (*pediatric Chloromycetin Palmitate*) the article was represented as a drug composed in part of Chloromycetin, and it was not from a batch with respect to which a certificate issued pursuant to law was effective.

503 (b) (4)—(*Butisol Sodium capsules [Mol-Iron tablets], Bicillin-Sulfas tablets, Diamox tablets, Erythrocin, Thorazine, Cortril tablets, and Paredrine-Sulfathiazole Suspension*) the articles were drugs subject to 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

All articles were adulterated and/or misbranded while held for sale.

The libel alleged also that 12 other products were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 2-14-56. Default—destruction.

#### DRUGS FOR VETERINARY USE

4987. Birdie-Tabs. (F. D. C. No. 38420. S. No. 26-804 M.)

QUANTITY: 25 boxes, 12 6-tablet vials each, at New Orleans, La.

SHIPPED: 7-28-55 and 8-11-55, from Dallas, Tex., by Birdie-Cure Co.

ACCOMPANYING LABELING: (Display card) "Aureomycin Chlortetracycline Birdie-Tabs for Canaries and Parakeets \* \* \* Each 5 gr. tablet contains Aureomycin Chlortetracycline Veterinarian Soluble - 5 mg., Vit. B-12—0.1 mcg., Lactose, starch and kaolin" and circular entitled "Birdie-Gram."

LIBELED: 8-31-55, E. Dist. La.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was effective for stimulating appetite, resisting infection, protecting against disease, overcoming conditions that cause puffed-up feathers, lack of pep, sneezing, coughing, nasal discharge, watery eyes, loose droppings (diarrhea), gasping breath, and other symptoms of ill health in birds; and 502 (1)—the article was composed partly of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to law.

DISPOSITION: 4-17-56. Default—destruction.